



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/265,307	03/09/1999	NIGEL L. WEBB	N0260/7031(E)	4390

7590 01/13/2004

EDWARD R GATES
WOLF GREENFIELD AND SACKS
600 ATLANTIC AVENUE
BOSTON, MA 02210

EXAMINER

TRINH, BA K

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/265,307

Applicant(s)

WEBB ET AL.

Examiner

Ba K. Trinh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/30/2003 and 06/07/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,5,7,12,17,21,23,28,33,57,62,65,69,70,75,78,82,84,89,90,94,97,101,103,107,108,110,114,119-201 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 57,62,65,69,70,75,78,82,84,89,90,94,97,101,103,107,108,110,114,143-187 is/are allowed.

6) ☒ Claim(s) 1,5,7,12,17,21,23,33,119-121,123-126,128-131,134-136,139-142,188-201 is/are rejected.

7) ☒ Claim(s) 28,122,127,132-133,137-138 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>29</u> . | 6) <input type="checkbox"/> Other: |

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01)

Office Action Summary

Part of Paper No. 31

Art Unit: 1625

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 06/07/2003 has been entered

Claims 1, 5, 7, 12, 17, 21, 23, 28, 33, 57, 62, 65, 69, 70, 75, 78, 82, 84, 89, 90, 94, 97, 101, 103, 107, 108, 110, 114, 119 –201 are pending.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7, 12, 17, 21, 23, 33, 119-121, 123-126, 128-131, 134-136, 139-142, 188-201 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al, Kataoka et al and Rentsch et al.

Yoshida et al teaches an acyl derivative of arabinofuranosylcytosine (Ara-C) has better anti-leukemia than the parent; and can be used at high doses as compared to the maximum tolerance dose (MTD); note the summary and columns 1 and 2 page 1820 and Charts 1 and 2 in page 1821 of the reference. The acyl moiety contains an alkyl chain of 21 carbon atoms (or a fatty acid moiety) which is conjugated to Ara-C to form the acyl derivative (BH-AC). The initial dose was 500mg/m², and was then raised to 1,300mg/m², at which level the experiment

Art Unit: 1625

was stopped because a rash was observed. Kataoka et al teaches that the fatty acid endows Ara-C with hydrophobicity thus enables BH-AC to be released slowly in the body and would circulate in the body for a prolonged period of time; note the Summary and the Introduction in page 147 of the reference. Rentsch et al teaches hexadecyl and octadecyl of Ara-C (C₁₆ and C₁₈ fatty acid moieties) were active at molar concentrations one-sixteenth of those of Ara-C (the parent drug void of the acyl moiety); note the third paragraph in column 2 page 1076 and Figure 1. in page 1077 of the reference. Thus, the claimed invention would be deemed obvious over the teachings of the prior art since the addition of the fatty acid to the cancer drug (Ara-C) would enable the increase of the dosage of the conjugated drug without harming the body. The conjugated drug has lower solubility in the body fluid and is released slowly to the body, thus a higher dose can be used and tolerated as compared to the parent drug.

Claims 57, 62, 65, 69, 70, 75, 78, 82, 84, 89, 90, 94, 97, 101, 103, 107, 108, 110, 114, 143-187 are allowable.

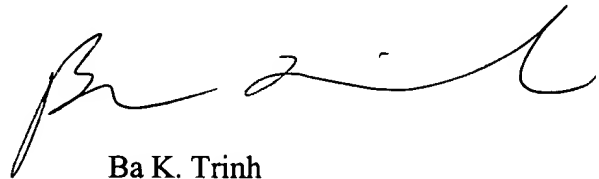
Claims 28, 122, 127, 132-133, 137-138 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba K. Trinh whose telephone number is (703) 308-4545. The examiner can normally be reached on Monday to Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman, can be reached on (703) 872-9306. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7922.

Art Unit: 1625

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Ba K. Trinh', written in a cursive style.

Ba K. Trinh
Primary Examiner
Art Unit 1625

TRINH/BKT

December 23, 2003